DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 29 1997

Re: Posicor®
Docket No. 97E-0462

#14

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,808,605 filed by Hoffman-La Roche,Inc. under 35 U.S.C. § 156. The human drug product identified in the patent extension application is Posicor® (mibefradil dihydrochloride), which was assigned New Drug Application (NDA) No. 20-689.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on June 20, 1997, which makes the submission of the patent term extension application on August 6, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: George W. Johnstone
Hoffman-La Roche, Inc.
Patent Law Department
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Nutley, NJ 07110